ABSTRACT

The present invention relates to the field of cancer immunotherapy. In particular, vaccines are administered in conjunction with high doses of cytokines to enhance an anti-tumor immune response.

Table 1: Patient characteristics

Patient No.	Age/Sex	Time from last vaccination to IFN-α	Initial disease	Disease at time of IFN-α	Current Status	Peak frequency of gp100-reactive T cells during vaccination*	Peak frequency of gp100-reactive T cells during HDI
M136	52/M	8 months	Lung, LN**	NED***	NED	$1/5x10^4$	$1/1x10^5$
M302	53/F	3 months	Skin metastases	NED	NED	1/510	1/263
M246	47/F	7 months	LN	NED	NED	$1/1x10^5$	$1/1x10^5$
M237	49/M	8 months	LN	NED	NED	1/6667	1/1667
M166	33/M	6 months	Mesenteric Mass	Gluteal mass	Clinical regression	1/6270	1/1111
M335	32/F	1.5 months	LN, skin, breast	LNs, skin, lung	Clinical regression	1/588	1/351
M260	64/M	17 months	LN	Lung	Lung (no change)	$1/2x10^4$	$1/1x10^5$

* The peak frequency was the highest number of spots during at any time-point during active vaccination.
ELISPOT assays wereperformed as described in the materials and methods and the average of three replicate wells is reported as 1/(average spot number/10^5 plated cells).
**LN = lymph node ***NED=no evaluable disease

Table 2

Toxicity, treatment delays, and dose reductions in patients receiving HDI after vaccination.

	Grade 3*	Grade 2	Total
Constitutional Symptoms	1/7	3/7	4/7
Vitiligo	0/7	1/7	1/7
Elevated Liver Function Tests	1/7	4/7	5/7
Granulocytopenia/leukopenia	1/7	6/7	7/7
Neurologic Toxicity	1/7	1/7	2/7
Dose reduction			7/7
Dose Delay			7/7

*The delivery of HDI was modified for each patient on the basis of common toxicity criteria,[15] with 4 being the most severe, necessitating stopping treatment. A 33% reduction of dosage occurred after the first treatment interruption and a 66% reduction from baseline dose occurred after the second. No patients had a third treatment interruption that would also have required removal from treatment.